

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 6

A1  
levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in the patient versus the normal human control is associated with a cancer which is progressing in stage and an increase is associated with a cancer which is regressing in stage or in remission.

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**REMARKS**

Claims 1-10 are pending in the instant application. Claims 6 and 8-10 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5 and 7 have been rejected. Claims 1-5 have been amended and claim 7 has been canceled in light of the amendments to claims 1-5. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Finality of Restriction Requirement**

The Examiner has made final the Restriction Requirement mailed May 6, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled non-elected claims 6 and 8-10, without prejudice. However, in light of the finality of the Restriction Requirement, Applicants

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 7

reserve the right to file a divisional application to the canceled subject matter.

## II. Information Disclosure Statement

The Examiner has indicated that references AD, AE, AQ, AR, AS and AU of the Information Disclosure Statement were not found in the instant application. As stated in the transmittal sheet forwarded with the IDS, these references were not provided with the Information Disclosure Statement as they are standard reference texts cited in the application for their teachings of general procedures known to those of skill in the art. It is Applicants' belief that the United States Patent Office has access to these standard reference texts and due to the voluminous nature, copies are not being provided. Further, these general teachings of procedures do not affect the novelty or unobviousness of the instant claimed invention.

## III. Rejection of Claims 1-5 and 7 under 35 U.S.C. § 112, first paragraph

Claims 1-5 and 7 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 8

nearly connected, to make and/or use the invention. Specifically, the Examiner suggests that there is no nexus between the GSG identified as SEQ ID NO:3 and the GSGs, Cln114 and Cln115 for which data is presented in the specification. Further, the Examiner suggests that Applicants have not provided any disclosure enabling the use of variant and degenerate polynucleotides of SEQ ID NO:3. In addition, the Examiner suggests that Applicants have not set forth any supporting evidence that suggests that SEQ ID NO:3 is a unique tumor or molecular marker for gastrointestinal cancer.

Applicants respectfully traverse this rejection.

In Figure 3 of U.S. Provisional Application No. 60/188,061, filed March 9, 2000, from which the instant application claims priority, the nucleic acid sequence of Cln115 (SEQ ID NO:3) is disclosed. A courtesy copy of the Figures from the as-filed provisional application is provided herewith.

Figure 3 from the priority application establishes the nexus between Cln115 and SEQ ID NO:3.

Further, at page 4 of the Office Action, the Examiner acknowledges that the evidence presented in the specification suggests that with the occurrence of Cln114 and Cln115 underexpression in colon cancer, this can be interpreted as

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 9

diagnostic of gastrointestinal cancer. Thus, since the nexus between Cln115 and SEQ ID NO:3 has now been established, this evidence in the specification must also be indicative of SEQ ID NO:3 being a unique tumor or molecular marker for gastrointestinal cancer.

In addition, and without conceding the correctness of the Examiner's position, Applicants have amended the claims to exclude the use of variant and degenerate polynucleotides of SEQ ID NO:3.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested in light of these amendments.

**IV. Rejection of Claims 1-5 and 7 under 35 U.S.C. § 112, second paragraph**

Claims 1-5 and 7 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that claims 1-5 and 7 are vague and indefinite in the recitation of "GSG". The Examiner also suggests that the claims 1-5 are vague and indefinite in the recitation of "determining GSG

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 10

levels" because it is not clear what type of GSG molecule is measured. Claim 7 is also suggested to be indefinite in the recitation of non-elected subject matter, namely reference to claim 6 and SEQ ID NO:1.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 1-5 to delete the term GSG and clarify that the molecule determined comprises SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3. Support for this amendment is provided in the specification at pages 4-5. Claim 7 has been canceled in light of amendments to claims 1-5.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

**V. Rejection of Claims 1-5 and 7 under 35 U.S.C. § 101**

Claims 1-5 and 7 have been rejected under 35 U.S.C. § 101 as not being supported by either a specific, substantial, credible or asserted utility or a well established utility.

Applicants respectfully traverse this rejection.

As discussed in Section III, *supra*, evidence establishing the nexus between SEQ ID NO:3 and Cln115 was set forth in the provisional application from which the instant application claims

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 11

priority. A courtesy copy of Figure 3 from U.S. provisional application serial No. 60/188,061 with the nucleic acid sequence of Cln115 (SEQ ID NO: 3) is provided herewith. Further, the claims have been amended and are now drawn to determination of levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3. Claim 7 has been canceled in light of the amendments to claims 1-5.

As also discussed in Section III, *supra*, the specification has been acknowledged by the Examiner to provide evidence of the usefulness of Cln115, and thus SEQ ID NO:3, as a tumor diagnostic marker.

Accordingly, the claims as amended are clearly supported by a specific, substantial, credible utility.

Withdrawal of this rejection is therefore respectfully requested.

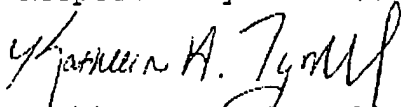
#### VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 12

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



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Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 13

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 6-10 without prejudice.

Please amend the claims as follows:

1. (amended) A method for diagnosing the presence of gastrointestinal cancer in a patient comprising:

(a) determining levels of ~~656~~ SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3 in cells, tissues or bodily fluids in a patient; and

(b) comparing the determined levels of ~~656~~ SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3 with levels of ~~656~~ SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3 in cells, tissues or bodily fluids from a normal human control, wherein a change in determined levels of ~~656~~ SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3 in said patient versus normal human control is associated with the presence of gastrointestinal cancer.

2. (amended) A method of diagnosing metastases of



Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 14

gastrointestinal cancer in a patient comprising:

(a) identifying a patient having gastrointestinal cancer that is not known to have metastasized;

(b) determining GSG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in a sample of cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined GSG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 with levels of GSG SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissue, or bodily fluid of a normal human control, wherein a decrease in determined GSG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in the patient versus the normal human control is associated with a cancer which has metastasized.

3. (amended) A method of staging gastrointestinal cancer in a patient having gastrointestinal cancer comprising:

(a) identifying a patient having gastrointestinal cancer;

(b) determining GSG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 15

antisense sequence of SEQ ID NO: 3 in a sample of cells, tissue, or bodily fluid from said patient; and

(c) comparing determined ~~GGG~~ levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 with levels of ~~GGG~~ SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissues, or bodily fluid of a normal human control, wherein a decrease in determined ~~GGG~~ levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in said patient versus the normal human control is associated with a cancer which is progressing and an increase in the determined ~~GGG~~ levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 is associated with a cancer which is regressing or in remission.

4. (amended) A method of monitoring gastrointestinal cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having gastrointestinal cancer that is not known to have metastasized;

(b) periodically determining levels of ~~GGG~~ SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 16

antisense sequence of SEQ ID NO: 3 in samples of cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined ~~656~~ levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 with levels of ~~656~~ SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissues, or bodily fluid of a normal human control, wherein a decrease in any one of the periodically determined ~~656~~ levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in the patient versus the normal human control is associated with a cancer which has metastasized.

5. (amended). A method of monitoring a change in stage of gastrointestinal cancer in a patient comprising:

(a) identifying a patient having gastrointestinal cancer;  
(b) periodically determining levels of ~~656~~ SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined ~~656~~ levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 17

conditions to the antisense sequence of SEQ ID NO: 3 with levels  
of ~~696~~ SEQ ID NO:3 or a polynucleotide which hybridizes under  
stringent conditions to the antisense sequence of SEQ ID NO: 3 in  
cells, tissues, or bodily fluid of a normal human control,  
wherein a decrease in any one of the periodically determined ~~696~~  
levels of SEQ ID NO:3 or a polynucleotide which hybridizes under  
stringent conditions to the antisense sequence of SEQ ID NO: 3 in  
the patient versus the normal human control is associated with a  
cancer which is progressing in stage and an increase is  
associated with a cancer which is regressing in stage or in  
remission.

**Figure 1: Nucleic Acid Sequence of Cln114 (SEQ ID NO:1)**

ACTCCCCTCCGAGGGGTCTGACCACGCTTGGGCCGAGTCATACGCCCACGCGTCCGGGAC  
 CTCCTGCCCTCAGGTGATCCATCCACCTCGGCCAGTCAAAGTGCTGGGATTACAGGCATGA  
 GCCATTGCACCCAGCCGATACTACTATATCCCCATTTTACAGATGAGCACATGGGCAAATTG  
 AGGGTAAGGCACTGACCCATGATCATAAGCTGAGAAGTGCGAAAGGCAGGATTTGAACC  
 TAGAACCTCTGGCTCCACACACTAGTAATCTAAACCACTCTCCCTACAATACAACATACG  
 TGGTAAAGATGTGTGGTGGGCACGCAATCAACGTAGGTCCCTTCACAGTTGCTGGGAGAG  
 GCAGGAATTTGCAGTTCCTCCGCGTTCTCCTCCTCCGCTGCCACCTGTCTGGGTGATT  
 CCTGCAGCCTGCCCTGCCCTGCCTGGTCTCACCTCCTCTGCCAACAGAAGTCTGGGCA  
 GGTTTTTATGGGCTCTGATAAGGCCCTGGCAGGGCCGAAGTTCATGAGCACTTCTCTTT  
 GCAGGAGGGCGTAGGGGAGGGGACCCAGGTGATTGGGTCTGGCTGGTCAACAGCGAAG  
 CTGGCAAGGGAAGGGAGACTAGGGTGCCTCTAGGACAAGCCGACAGCCTGAGAGTCCAGAA  
 GAGGAGCCCTGTGGACCTCCTCCTGCCAGCCACTCCTTACCCTGGGTATAAGAGCCACC  
 ACCGCCTGCCATCCGCCACCATCTCCCACTCCTGCAGCTCTTCTCACAGGACCAGCCACT  
 ACCGCAGCCTCGAGCGATGGCCTATGTCCCCGACCCGGGCTACCAGCCCACCTACAACCC  
 GACGCTGCCCTTACTACCAGCCCATCCCGGGCGGGCTCAACGTGGGAATGTCTGTTTACAT  
 CCAAGGAGTGGCCAGCGAGCACATGAAGCGGTTCTTCGTGAACCTTTGTGGTTGGGCAGGA  
 TCCGGGCTCAGACGTCGCCTTCCACTTCAATCCGCGGTTTGACGGCTGGGACAAGGTGGT  
 CTTCACACGTTGCAGGGCGGGAAGTGGGGCAGCGAGGAGAGGAAGAGGAGCATGCCCTT  
 CAAAAGGGTGCCGCTTTGAGCTGGTCTTCATAGTCTCTGGCTGAGCACTACAAGGTGGT  
 GCTAAATGGAAATCCCTTCTATGAGTACGGGCACCGGCTTCCCTACAGATGGTCAACCA  
 CCTGCAAGTGGATGGGGATCTGCAACTTCAATCAATCAACTTCATCGGAGGCCAGCCCT  
 CCGGCCCCAGGGACCCCCGATGATGCCACCTTACCCTGGTCCCGGACATTGCCATCAACA  
 GCTGAACAGCCTGCCACCATGGAAGGACCCCCAACCTTCAACCCGCTGTGCCATATTT  
 CGGGAGGCTGCAAGGAGGGCTCACAGCTCGAAGAACCATCATCATCAAGGGCTATGTGCC  
 TCCCACAGGCAAGAGCTTTGCTATCAACTTCAAGGTGGGCTCCTCAGGGGACATAGCTCT  
 GCACATTAATCCCCGCATGCCCAACGGTACCGTGGTCCGGAACAGCCTTCTGAATGGCTC  
 GTGGGGATCCGAGGAGAAGAAGATCACCCACAACCCATTGTTGGTCCCGGACAGTTCTTTGA  
 TCTGTCCATTGCTGTGGCTTGGATCGCTTCAAGGTTTACGCCAATGGCCAGCACCTCTT  
 TGACTTTGCCCATCGCCTCTCGGCCTTCCAGAGGGTGGACACATTGGAAATCCAGGGTGA  
 TGTCACTTGTCTATGTCCAGATCTAATCTATCTCTGGGGCCATAACTCATGGGAAAC  
 AGAATTATCCCCTAGGACTCCTTTCTAAGCCCCTAATAAAATGTCTGAGGGTGTCTCATG

**Figure 2: Amino Acid Sequence (SEQ ID NO:2) encoded by Cln114**

MAYVPPAPGYOPTYNPTLPYYQPIPGGLNVGMSVYIQGVASEHMKRFFVNFVVGQDPGSDV  
 AFHFNPRFDGWDKVVFNLTQGGKKGSEERKRSMFPFKKGAAFELVFIVLAEHYKVVVVNGNP  
 FYEYGHRLPLQMVTHLQVDGDLQLQSINFIGGQPLRPQGPPMPPYPGPGHCHQQLNSLP  
 TMEGPPTFNPPVPYFGRLOGLTARTIIKGYVPPTGKSFAINFKVGSSGDIALHINPR  
 MGNGTVVRNSLLNGSWGSEKKITHNPFPGQFFDLSIRCLDRFKVYANGQHLFDFAHR  
 LSAFQRVDTLEIQGDVTLVYVQI

**Figure 3: Nucleic Acid Sequence of Cln115 (SEQ ID NO:3)**

CTTTAGCCCAACAGTCAAAAATAATTGATGCTACCCTACAAATGTCCAAAACCTCTAGTAT  
 ATCATATTTCTAAGTTACAGCAAATATTAGTCCCTGCTAAACCAGGGAGCTTTGGCAAAAA  
 TGTTTTTTGACAGTAAATTTGTCTTGATTATATTAATACTAGTCAAAGAGGTGTTTGTA  
 ACATTAATTAGAGCTTCTTGTTGTAGGTGGGTAAACACCACCAATCAAGAGGTCAATCTAA

CAGAAAGCCTGGATCAGAAAACCATCACCCCTAAAAAACATGCCTTACATATTTAACACA  
CTCTGAAATCCAGTCAAAATATGACTAAAGGCCCTTGCCATGACTGATGTATTCTCCTGG  
CCACGCCAAACAAATGGGAGCCTGGTTACGAGTCAGCCTTCAGGGACTTGTACATTTC  
TACTTGGTTTCTTCTTGTATTGTGCATAATAAAATGTTTTCTATGCTGTTTAGTGCAAC  
TTAGGCCCTATTCTGTAGAAGTCTCCTCTACTATTTCAGGCCACTCAAACACCCCAAATAA  
TTGAGTTCAAAATCGACATCAAGATATAAAGGAATCAGTGACTAAATATATTTTCATATAT  
GGTATTTTTATTGATTATTGTGCTGTCTTGACCTAGTATGGAGGCCTTGGCTAGAGGCTG  
GTCAGTTTCTCTCTTGAGCAGCTGATTAAATCCACACCCCAACCACTTCCCTTATCAGG  
TTCTCACACTCTGGGGCCACTATGTACCCACTCTAATCACCACAGGGCCAGACATCAGAC  
AATTAAGGACAGCGCCCATGCCCAAGCCCGCCAAAATTATGCAAATTATTCAAAATTA  
TTCAACCTAGCTAACCCCAACCCTTTTTGCTGTACATAAGCTGCCCATTCCTCCCTCCAGCC  
TGTGGTACCCAGTCCTCAGGTGCAACCCCTGCGTGGTCTCTGTGGCAGCCTTCTCTCA  
TTCAGAGCTGTTTTCCACAGAGGTAGTGAAAAGAACTGGATTTTCAAGTTCACCTTTGCAA  
GAGAAAAAGAAAACCTCAGTAGAAGATAATGGCAAGTCCAGACTGGGGATATGATGACAAA  
AATGGTCTGAAACAATGGAGCAAGCTGTATCCCATTGCCAATGGAAATAACCAATCCCTT  
GTTGATATTAAAACAGTGAAACCAAACATGACACCTCTCTGAAACCTATTAGTGTCTCC  
TACAACCCAGCCACAGCCAAAGAAATTATCAATGTGGGGCATTCTTTCCATGTAAATTTT  
GAGGACAACGATAACCGATCAGTGCTGAAAGGTGGTCCTTTCTCTGACAGCTACAGGCTC  
TTTCAGTTTCATTTTCACTGGGGCAGTACAAATGAGCATGGTTTCAAGACATACAGTGGAT  
GGAGTCAAAATATTCTGCCGAGCTTCACGTAGCTCACTGGAATTCTGCAAAGTACTCCAGC  
CTTGCTGAAGCTGCCTCAAAGGCTGATGGTTTGGCAGTTATTGGTGTTTTGTATGAAGTT  
GGTGAAGCCAAACCCAAACCTGCAGAAAGTACTTCAATGCCCTCCAAGCAATTAACCAAG  
GGCAACAGAGCCCCATTACAAATTTTGACCCCTCTACTCTCCTTCCTTCATCCCTGGAT  
TTCTGGACCTACCCTGGCTCTCTGACTCATCCTCTCTTTATGAGAGTGTAACTTGGATC  
ATCTGTAAGGAGAGCATCAGTGTGAGCTCAGAGCAGCTGGCACAAATCCGCAGCCTTCTA  
TCAAAATGTTGAAGGTGATAACGCTGTCCCCATGCAGCACAAACCGCCCCAACCAACCT  
CTGAAGGGCAGAACAGTGAGAGCTTCATTTTGATGATTCTGAGAAGAACTTGTCTCTCC  
TCAAGAACACAGCCCTGCTTCTGACATAATCCAGTTAAATAATAATTTTTTAAGAAATAA  
ATTTATTTCAATATTAGCAAGACAGCATGCCTTCAAATCAATCTGTAAACTAAGAACT  
TAAATTTTAGTTCTTACTGCTTAATTCAAATAATAATTAGTAAGCTAGCAAATAGTAATC  
TGTAAGCATAAGCTTATCTTAAATTCAAGTTTACTTTGAGGAATTCTTTAAAATTACAAC  
TAAGTGATTTGTATGTCTATTTTTTTCAGTTTATTTGAACCAATAAAATAATTTTATCTC  
TTTCTTTCTGTTGTGCATTCACTTCTAAAACCATTAAGTTTCTACTCCATTTCATTTCA  
AAAATCTTAAATACTTTACTTGAAGAGTATTTTGCTTCAAATACAAACCTTAAGAGCA  
GCTGGAGATGAAATATTGGGAAATTCATTTGCTTACTCCTGAAGACAAAAATATAGCTGA  
GATGACCACTGGATTTAATATCGTTATGCTGGCCCAACATTGCTACCATTGTGTGTCT  
GTGATCAAAATGATTATCTTTTATATAGGAAGATGACGCTTCTGGATATTGCTTTCACTT  
CTTCTCCCCACGTTAGCAAGGACAATGCTTCTCTGCCATTATTACAACCTAGTTAGTTTGC  
ATGGAGAATCTTTACTTTAAATTTGGAAGAAAAGTCACAAGTGAATGGTTTATAAAAATG  
CTAAAGAAGTCATTCTTCTTAGAATCATATAGAAACATCATGCAATCTTTTAGTCAGAT  
GTGCGCTTACCTTATGCTATTTTTATCTTTAATTGACACACAATAATTGTACATGTTTA  
TGGAGTATAGTGTGGTGTCTTCTGTTTGTGTTGTTTGTGTTTGTGAGACAAGGTCTCACTCT  
GCCAGTCAGGGTGGAGTGGATGGT

Figure 4: Amino Acid Sequence (SEQ ID NO:4) encoded by Cln115

MASPDWGYDDKNGPEQWSKLYPIANGNNQSPVDIKTSETKHDTSLKPISVSYNPATAKEI  
INVGHSHFVNFDNDNRSVLKGGPFSDSYRLFQPHFWGSTNEHGSEHTVDGVKYSAELH  
VAHWNSAKYSSLAEAASKADGLAVIGVLMKVGEANPKLQKVLDAALQAIKTKGKRAPFTNF  
DPSTLLPSSLDFTYPCSLTHPPLYESVTWIIICKESI SVSSEQLAQFRSLLSNVEGDNAV  
PMQHNNRPTQPLKGRTVRASF